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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,656	07/17/2000	Alexander V. Kabanov	UNMC 63117A-	1208

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DANN DORFMAN HERRELL & SKILLMAN
SUITE 720
1601 MARKET STREET
PHILADELPHIA, PA 19103-2307

EXAMINER

NGUYEN, HELEN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/445,656

Applicant(s)

KABANOV ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

The amendment of paper no. 9, filed February 8, 2002, is acknowledged. All arguments have been fully considered.

Claims 8, 11 and 15 are amended.

Claims 1-18 are still pending and presented for examination.

Abstract objection

The objection to the abstract set forth in the previous Office Action of paper no. 7, is hereby withdrawn due to the amendment in paper no. 9.

Claim rejection- 35 USC § 112

The rejection of claims 1-18 of record set forth under 35 U.S.C. 112, Second Paragraph, is hereby withdrawn.

Double Patenting & Obvious Double Patenting rejection

The rejections of record under Double Patenting & Obvious Double Patenting set forth in previous office action of paper no. 7 are hereby withdrawn.

Claim rejection- 35 USC § 103

Applicants' arguments regarding the rejection under 35 U.S.C. 103 set forth in the previous office action of paper no. 7 have been considered,

but they are not persuasive. Therefore, the rejection under 35 U.S.C 103 is maintained for reason as follows.

The following is a quotation of **35 U.S.C. 103(a)** which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbell et al. (US Patent No. 5,410,016) in view of Ahmad et al. (US Patent No. 5,112,611) and Nakayama et al. (US Patent No. 5,531,917) and Weiner et al. (US Patent No. 5,171,737).

Hubbell et al. teach block copolymers comprising a water soluble region such as polyethylene glycol and a biodegradable region such as polylactic or polyamino acid (column 7, line 6 to column 8, line 68).

Controlled drug delivery of active agents such as enzymes from devices such as microspheres is disclosed (column 10, lines 29-48).

Hubbell et al. do not teach a charged surfactant having a biological activity.

Ahmad et al. teach papain for aiding human digestion (abstract).

Controlled release is disclosed (column 3, lines 7-11).

Nakayama et al. teach the stabilization of a proteolytic enzyme with a surfactant (abstract). Combinations of nonionic, anionic, and amphoteric surfactants are specified (column 2, line 62 bridging column 3, line 12). Papain is disclosed (column 3, lines 17-18). Sodium lauroyl sarcosinate and lauryl dimethylaminoacetic betaine are specified (column 5 and 6, Table 1).

Weiner et al. teach dioleoyl phosphatidylethanolamine (DOPE) and dioleoyl phosphatidylcholine (DOPC) as surfactants use for delivery of bioactive agents (abstract, column 2, lines 28-34).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to deliver papain with the device of Hubbell et al to achieve the beneficial effect of aiding human digestion in view of Ahmad et al. and to add surfactants to achieve the beneficial effect of stabilizing the enzyme in view of Nakayama et al.

As to the claimed complex, it is argued that such is inherently formed during mixing of the components to make the obvious composition. As to the particular claimed polyanionic and polycationic segments of the claimed

block copolymer, polyaspartic acid and polylysine are well known in the art as commercially available polyamino acids for the Hubbell et al.

biodegradable region.

As to the claimed nonionic surfactants, one of ordinary skill would use DOPE or DOPC as such because their utility for delivering bioactive agents in view of Wiener et al.

As to the claimed biologically active surfactant, sarcosine is well known as a metabolic intermediate.

As to the claims weight percent, it is within the skill in the art to select optimal parameters such as ratios or weight percents of components in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 19880). Therefore, the ratios or weight percents instantly claimed are not considered critical absent evidence showing unexpected and superior results.

- Regarding Hubbell et al., Applicants argue that Hubbell et al. teach cross-linked polymers. However, Applicants do not exclude cross-linked polymers.
- Applicants argue that Nakayama et al. specifically do not teach surfactants having an opposite charge to that of the copolymer.

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However, Nakayama et al. teach a mixture of surfactants which include the claimed oppositely charged surfactants.

- Applicants argue that both Nakayama et al. and Weiner et al. are nonanalogous art. However, Nakayama is used only for its teaching of stabilization of proteolytic enzyme. Regarding Weiner et al., Weiner is cited only for its teaching of particular surfactants compatible with a bioactive agent.
- Applicants argue that there is no motivation to combine. However, motivation is provided.

Conclusion

Claims 1-18 are rejected.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached at (703) 308-4432 or her supervisor, Minna Moezie can be reached at (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Helen Nguyen
Patent Examiner

March 19, 2002


EDWARD J. WEBMAN
PRIMARY EXAMINER